

## REMARKS

Applicant wishes to thank the Examiner for extending the courtesy of a telephonic interview with the Applicant's representatives, Mark R. Benedict and Raymond D. Smith on May 16, 2008.

Claims 2, 5, 14, 15 and 17 are presently pending. Claims 1, 3 and 4 have been canceled without prejudice. Claim 2 is amended to include the scope of claims 1, 3 and 4, and by adding the limitation "selecting an LXR agonist that exhibits a greater effect on expression of an inflammatory gene than on expression of a lipid metabolism gene." Support for the "selecting" step is found in the Specification as filed at page 21-22, paragraph [0080].

Claim 17 was not included with elected group I claims. However, in light of the amendment to Claim 17, which makes it depend from Claim 2, the Applicants respectfully requests inclusion of Claim 17 with the Group I claims currently under examination.

No new matter has been added herewith. The following addresses the substance of the Office Action.

### Indefiniteness

Claim 15 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. In particular, the claim was said to lack antecedent basis because the base Claim 1 did not address "inflammatory disease." Claim 15 is amended to be dependent on Claim 14, which provides antecedent basis for an inflammatory disease or condition. Support for the amendment is found in the Specification as filed at page 4, paragraph [0016]. Accordingly, the Applicants respectfully request removal of the rejection.

### Enablement

Claims 1-5, 14 and 15 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for particular liver X receptor (LXR) agonists, allegedly does not reasonably provide enablement for any LXR agonist. Applicants have amended Claim 2 to limit the LXR agonists employed by the claimed methods to those that are selected to exhibit a greater effect on expression of an inflammatory gene than on expression of a lipid metabolism gene. The Specification enables the use of this subclass of LXR agonists by providing an example of how such agonists can be identified (e.g., by DNA microarray analysis discussed at page 21, paragraph [0080]) and by giving two working examples of such LXR agonists, (i.e.,

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compounds GW3965 and T0901317. In view of the amendments to the claims and the preceding remarks, the Applicants respectfully request withdrawal of the rejection.

#### **Anticipation**

Claims 1-5 and 14 and 15 were rejected under 35 U.S.C. § 102(e) as anticipated by a plurality of references, for example by Elias et al. (U.S. Patent No. 6,184,215), Song et al. (U.S. Patent No. 7,078,396), and Martin et al. (U.S. Patent No. 7,115,640). The cited references teach the use of agonists of liver X receptors for treating inflammation, including atherosclerosis. However, the cited references do not disclose methods that include the step of selecting an LXR agonist that exhibits a greater effect on expression of an inflammatory gene than on expression of a lipid metabolism gene. Thus, the cited references do not anticipate each and every limitation of the claims. Accordingly, the Applicants respectfully request removal of the rejection.

#### **Obviousness**

Claims 1-5 and 14 were rejected under 35 U.S.C. § 103(a) as obvious over Ohlsson et al. 1996 *Clin Invest* 98:78-89, as evidenced by Elias et al. (U.S. Patent No. 6,184,315). Ohlsson et al. teaches that oxysterols inhibit binding of transcription factor AP-1 to DNA in macrophages, and thus reduces inflammatory response of macrophages. As discussed above, the claims have been amended to recite a method that includes the step of selecting an LXR agonist that exhibits a greater effect on expression of an inflammatory gene than on expression of a lipid metabolism gene. In light of the amendments to the claims, the claimed invention is not obvious in view of the cited references because the use of oxysterols by Ohlsson et al. does not provide any reason for one of skill in the art to (1) select an LXR agonist that exhibits a greater effect on expression of an inflammatory gene than on expression of a lipid metabolism gene, and (2) to administer to a mammal an amount of an LXR agonist, wherein the amount is sufficient to treat the disease or condition without a significant effect on lipid metabolism.. The claimed invention provides an advantage that is not appreciated or even considered by the prior art, namely avoidance of side effects related to unfavorably impacting lipid metabolism-related gene expression. Accordingly, the Applicants respectfully request removal of the rejection under 35 U.S.C. § 103(a).

#### No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this

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application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

### CONCLUSION

In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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